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CALIFORNIA LEGISLATURE—2015–16 REGULAR SESSION

ASSEMBLY BILL

No. 1386

Introduced by Assembly Member Low

February 27, 2015

An act to add Section 4119.4 to the Business and Professions Code, to amend Section 1714.23 of the Civil Code, and to amend Section 1797.197a of the Health and Safety Code, relating to emergency medical care.

LEGISLATIVE COUNSEL'S DIGEST

AB 1386, as amended, Low. Emergency medical care: epinephrine auto-injectors.

(1) Existing law authorizes a prehospital emergency medical care person, first responder, or lay rescuer to use an epinephrine auto-injector to render emergency care to another person, as specified. Existing law requires the Emergency Medical Services Authority to approve authorized training providers and the minimum standards for training and the use and administration of epinephrine auto-injectors. The existing Pharmacy Law, also authorizes a pharmacy to dispense epinephrine auto-injectors to a prehospital emergency medical care person, first responder, or lay rescuer for the purpose of rendering emergency care in accordance with these provisions. A violation of the Pharmacy Law is a crime.

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This bill would permit an "authorized entity," as defined, to use an epinephrine auto-injector to render emergency care to another person in accordance with these provisions. The bill would also authorize a pharmacy to furnish epinephrine auto-injectors to an authorized entity pursuant to those provisions. Because a violation of these provisions would be a crime, the bill would impose a state-mandated local program. The bill would require an authorized entity to create and maintain a specified operations plan relating to its use of epinephrine auto-injectors, and would require those entities to submit a report to the State Department of Public Health on incidents related to the administration of epinephrine auto-injectors. The bill would also require the department to issue an annual report summarizing and analyzing the reports submitted to the department pursuant to the bill's provisions.

(2) Under existing law, everyone is generally responsible, not only for the result of his or her willful acts, but also for an injury occasioned to another by his or her want of ordinary care or skill in the management of his or her property or person, except so far as the latter has, willfully or by want of ordinary care, brought the injury upon himself or herself. Existing law also provides that a prehospital emergency care person, first responder, or lay rescuer who administers an epinephrine auto-injector to another person who appears to be experiencing anaphylaxis at the scene of an emergency situation, in good faith and not for compensation, is not liable for any civil damages resulting from his or her acts or omissions in administering the epinephrine auto-injector, if that person has complied with specified certification and training requirements and standards.

This bill would provide that employees, agents, any employee, agent, or other trained—individuals individual of an authorized entity who administers an epinephrine auto-injector to another person who appears to be experiencing anaphylaxis at the scene of an emergency situation, in good faith and not for compensation, is not liable for any civil damages resulting from his or her acts or omissions in administering the epinephrine auto-injector, if that person has complied with specified certification and training requirements and standards. The bill would also provide that an authorized entity-located in this state shall not be liable, in this state, for any injuries or related damages that result from the provision or administration of an epinephrine auto-injector by its employees or agents outside of this state if the entity or its employee or agent would not have been liable for those injuries or related damages had the provision or administration occurred within this state. is not

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liable for any civil damages resulting from any act or omission connected to the administration of an epinephrine auto-injector, as specified.

(3)The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: yes.

The people of the State of California do enact as follows:

- 1 SECTION 1. Section 4119.4 is added to the Business and 2 Professions Code, to read:
- 4119.4. (a) Notwithstanding any other law, a pharmacy may furnish epinephrine auto-injectors to an authorized entity, as defined by Section 1797.197a of the Health and Safety Code, if both of the following requirements are met:
 - (1) The epinephrine auto-injectors are furnished exclusively for use at or in connection with an authorized entity. the possession of an authorized entity and for use by its employees, volunteers, and agents, first responder, or by a family member or caregiver of the person who appears to be experiencing anaphylaxis, as defined by paragraph (1) of subdivision (a) of Section 1714.23 of the Civil Code, or by the person who appears to be experiencing anaphylaxis, as defined by paragraph (1) of subdivision (a) of Section 1714.23 of the Civil Code.
- 16 (2) An authorized health care provider provides a prescription 17 that specifies the quantity of epinephrine auto-injectors to be 18 furnished.
 - (b) The pharmacy shall label each epinephrine auto-injector dispensed with all of the following:
- 21 (1) The name of the person or entity to whom the prescription 22 was issued.
- (2) The designations "Section 1797.197a Responder" and "FirstAid Purposes Only."
 - (3) The dosage, use, and expiration date.

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(c) Each dispensed prescription shall include the manufacturer's
product information sheet for the epinephrine auto-injector.

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(d) Records regarding the acquisition and disposition of epinephrine auto-injectors furnished pursuant to subdivision (a) shall be maintained by the authorized entity for a period of three years from the date the records were created. The authorized entity shall be responsible for monitoring the supply of epinephrine auto-injectors and ensuring the destruction of expired epinephrine auto-injectors.

- (e) The epinephrine auto-injector dispensed pursuant to this section may be used only for the purpose, and under the circumstances, described in Section 1797.197a of the Health and Safety Code.
- SEC. 2. Section 1714.23 of the Civil Code is amended to read: 1714.23. (a) For purposes of this section, the following definitions shall apply:
- (1) "Anaphylaxis" means a potentially life-threatening hypersensitivity or allergic reaction to a substance.
- (A) Symptoms of anaphylaxis may include shortness of breath, wheezing, difficulty breathing, difficulty talking or swallowing, hives, itching, swelling, shock, or asthma.
- (B) Causes of anaphylaxis may include, but are not limited to, insect stings or bites, foods, drugs, and other allergens, as well as idiopathic or exercise-induced anaphylaxis.
- (2) "Epinephrine auto-injector" means a disposable drug delivery system with a spring-activated concealed needle that is designed for emergency administration of epinephrine to provide rapid, convenient first aid for persons suffering from anaphylaxis.
- (b) (1) Any person described in subdivision (b) of Section 1797.197a of the Health and Safety Code or employees, agents, or other trained individuals of an authorized entity, as defined by paragraph (2) of subdivision (a) of Section 1797.197a of the Health and Safety Code, who administers an epinephrine auto-injector, in good faith and not for compensation, to another person who appears to be experiencing anaphylaxis at the scene of an emergency situation is not liable for any civil damages resulting from his or her acts or omissions in administering the epinephrine auto-injector, if that person has complied with the requirements and standards of Section 1797.197a of the Health and Safety Code.
- (2) An authorized health care provider that prescribes or dispenses an epinephrine auto-injector or a pharmacist that dispenses an epinephrine auto-injector to a person described in

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subdivision (b) of Section 1797.197a of the Health and Safety Code or an authorized entity is not liable for any civil damages resulting from any act or omission related to the provision of an epinephrine auto-injector.

- (3) A person that conducts the training described in subdivision (c) of Section 1797.197a of the Health and Safety Code is not liable for any civil damages resulting from any act or omission related to the acquisition, possession, administration, or provision of an of the lay rescuer, as defined by paragraph (4) of subdivision (a) of Section 1797.197a of the Health and Safety Code, who renders emergency care by administering the epinephrine auto-injector.
- (4) (A) An authorized entity-located in this state shall not be liable, in this state, for any injuries or related damages that result from the provision or for any civil damages resulting from any act or omission other than an act or omission constituting gross negligence or willful or wanton misconduct connected to the administration of an epinephrine auto-injector by its employees or agents outside of this state if the entity or its employee or agent would not have been liable for those injuries or related damages had the provision or administration occurred within this state. any one of its employees, volunteers, or agents who is a lay rescuer, as defined by paragraph (4) of subdivision (a) of Section 1797.197a of the Health and Safety Code, or who, in good faith, and not for compensation, renders emergency medical or nonmedical care at the scene of an emergency.
- (5) An authorized entity that possesses and makes available epinephrine auto-injectors, including third parties that facilitate the availability of epinephrine auto-injectors to an authorized entity, is not liable for any injuries or related damages that result from any act or omission taken pursuant to this section.
- (B) The failure of an authorized entity to possess or administer an epinephrine auto-injector shall not result in civil liability.

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(5) This subdivision does not eliminate, limit, or reduce affect any other immunity or defense that may otherwise be is available under state law. law, including, but not limited to, the immunity from liability for any civil damages resulting from any act or omission other than an act or omission constituting gross negligence or willful or wanton misconduct of a person who in

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good faith, and not for compensation, renders emergency medical or nonmedical care at the scene of an emergency as provided by section 1799.102 of the Health and Safety Code.

- (c) The protection specified in subdivision (b) shall not apply in a case of personal injury or wrongful death that results from the gross negligence or willful or wanton misconduct of the person who renders emergency care treatment by the use of an epinephrine auto-injector.
- (d) Nothing in this section relieves a manufacturer, designer, developer, distributor, or supplier of an epinephrine auto-injector of liability under any other applicable law.
- SEC. 3. Section 1797.197a of the Health and Safety Code is amended to read:
- 1797.197a. (a) For purposes of this section, the following definitions shall apply:
- (1) "Anaphylaxis" means a potentially life-threatening hypersensitivity or allergic reaction to a substance.
- (A) Symptoms of anaphylaxis may include shortness of breath, wheezing, difficulty breathing, difficulty talking or swallowing, hives, itching, swelling, shock, or asthma.
- (B) Causes of anaphylaxis may include, but are not limited to, insect stings or bites, foods, drugs, and other allergens, as well as idiopathic or exercise-induced anaphylaxis.
- (2) "Authorized entity" means any for-profit, nonprofit, or government entity or organization in connection with, or at which, allergens capable of causing anaphylaxis may be present, including, but not limited to, recreation camps, colleges and universities, day care facilities, youth sports leagues, amusement parks, restaurants, places of employment, and sports arenas. that employs at least one person or utilizes at least one volunteer or agent that has voluntarily completed a training course as described in subdivision (c).
- (3) "Epinephrine auto-injector" means a disposable drug delivery system with a spring-activated concealed needle that is designed for emergency administration of epinephrine to provide rapid, convenient first aid for persons suffering from anaphylaxis.
- (4) "Lay rescuer" means any person who has met the training standards and other requirements of this section but who is not otherwise licensed or certified to use an epinephrine auto-injector on another person.

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(5) "Prehospital emergency medical care person" has the same meaning as defined in paragraph (2) of subdivision (a) of Section 1797.189.

- (b) A prehospital emergency medical care person, lay rescuer, or employees, agents, or other trained individuals of an authorized entity person or lay rescuer may use an epinephrine auto-injector to render emergency care to another person if all of the following requirements are met:
- (1) The epinephrine auto-injector is legally obtained by prescription from an authorized health care provider or from an authorized entity that acquired the epinephrine auto-injector pursuant to subdivision (e). An authorized health care provider may issue a prescription for an epinephrine auto-injector to a person described in this subdivision for the purpose of rendering emergency care to another person, upon presentation of current certification demonstrating that person is trained and qualified to administer an epinephrine auto-injector as a prehospital emergency medical care person or lay rescuer, pursuant to this section or any other statute or regulation.
- (2) The epinephrine auto-injector is used on another, with the expressed or implied consent of that person, to treat anaphylaxis.
- (3) The epinephrine auto-injector is stored and maintained as directed by the manufacturer's instructions for that product.
- (4) The person using the epinephrine auto-injector has successfully completed a course of training with an authorized training provider, as described in subdivision (c), and has current certification of training issued by the provider.
- (5) The epinephrine auto-injectors obtained by prehospital emergency medical care personnel pursuant to Section 4119.3 of the Business and Professions Code shall be used only when functioning outside the course of the person's occupational duties, or as a volunteer, pursuant to this section.
- (6) The Emergency Medical Services System is activated as soon as practicable when an epinephrine auto-injector is used.
- (c) (1) The authorized training providers shall be approved, and the minimum standards for training and the use and administration of epinephrine auto-injectors pursuant to this section shall be established and approved, by the authority. The authority may designate existing training standards for the use and administration of epinephrine auto-injectors by prehospital

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1 emergency medical care personnel to satisfy the requirements of this section.

- (2) The minimum training and requirements shall include all of the following components:
- (A) Techniques for recognizing circumstances, signs, and symptoms of anaphylaxis.
- (B) Standards and procedures for proper storage and emergency use of epinephrine auto-injectors.
- (C) Emergency followup procedures, including activation of the Emergency Medical Services System, by calling the emergency 9-1-1 telephone number or otherwise alerting and summoning more advanced medical personnel and services.
- (D) Compliance with all regulations governing the training, indications, use, and precautions concerning epinephrine auto-injectors.
- (E) Written material covering the information required under this provision, including the manufacturer product information sheets on commonly available models of epinephrine auto-injectors.
- (F) Completion of a training course in cardiopulmonary resuscitation and the use of an automatic external defibrillator (AED) for infants, children, and adults that complies with regulations adopted by the authority and the standards of the American Heart Association or the American Red Cross, and a current certification for that training.
- (3) Training certification shall be valid for no more than two years, after which recertification with an authorized training provider is required.
- (4) The director may, in accordance with regulations adopted by the authority, deny, suspend, or revoke any approval issued under this subdivision or may place any approved training provider on probation upon a finding by the director of an imminent threat to public health and safety, as evidenced by any of the following:
 - (A) Fraud.
 - (B) Incompetence.
- (C) The commission of any fraudulent, dishonest, or corrupt act that is substantially related to the qualifications, functions, or duties of training program directors or instructors.
- (D) Conviction of any crime that is substantially related to the qualifications, functions, or duties of training program directors

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or instructors. The record of conviction or a certified copy of the record shall be conclusive evidence of the conviction.

- (E) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of, or conspiring to violate, any provision of this section or the regulations promulgated by the authority pertaining to the review and approval of training programs in anaphylaxis and the use and administration of epinephrine auto-injectors, as described in this subdivision.
- (d) (1) The authority shall assess a fee pursuant to regulation sufficient to cover the reasonable costs incurred by the authority for the ongoing review and approval of training and certification under subdivision (c).
- (2) The fees shall be deposited in the Specialized First Aid Training Program Approval Fund, which is hereby created in the State Treasury. All moneys deposited in the fund shall be made available, upon appropriation, to the authority for purposes described in paragraph (1).
- (3) The authority may transfer unused portions of the Specialized First Aid Training Program Approval Fund to the Surplus Money Investment Fund. Funds transferred to the Surplus Money Investment Fund shall be placed in a separate trust account, and shall be available for transfer to the Specialized First Aid Training Program Approval Fund, together with the interest earned, when requested by the authority.
- (4) The authority shall maintain a reserve balance in the Specialized First Aid Training Program Approval Fund of 5 percent of annual revenues. Any increase in the fees deposited in the Specialized First Aid Training Program Approval Fund shall be effective upon determination by the authority that additional moneys are required to fund expenditures pursuant to subdivision (c).
- (e) An authorized health care provider may prescribe epinephrine auto-injectors to an authorized entity or to an employee or agent of an authorized entity who holds a valid certification demonstrating that the person is trained and qualified to administer an epinephrine auto-injector as a lay rescuer. entity. Epinephrine auto-injectors acquired by an authorized entity shall be stored in a location readily accessible in an emergency and in accordance with the epinephrine auto-injectors instructions for use and any additional requirements that may be established by the authority.

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(f) An authorized entity that possesses and makes available epinephrine auto-injectors shall do both of the following:

- (1) Create and maintain on its premises an operations plan that includes all of the following:
- (A) The name and contact number for the authorized health care provider who prescribed the epinephrine auto-injector.
 - (B) Where and how the epinephrine auto-injector will be stored.
- (C) The names of the designated employees or agents who have completed the training program required by this section and who are authorized to administer the epinephrine auto-injector.
- (D) How and when the epinephrine auto-injector will be inspected for an expiration date.
- (E) The process to replace the expired epinephrine auto-injector, including the proper disposal of the expired epinephrine auto-injector.
- (2) Submit to the State Department of Public Health, on a form developed by the State Department of Public Health, a report of each incident on the authorized entity's premises that involves the administration of an epinephrine auto-injector. The State Department of Public Health shall annually publish a report that summarizes and analyzes all reports submitted to it under this subdivision.
- (g) This section shall not apply to a school district or county office of education, or its personnel, that provides and utilizes epinephrine auto-injectors to provide emergency medical aid pursuant to Section 49414 of the Education Code.
- (h) This section shall not be construed to limit or restrict the ability of prehospital emergency medical care personnel, under any other statute or regulation, to administer epinephrine, including the use of epinephrine auto-injectors, or to require additional training or certification beyond what is already required under the other statute or regulation.
- SEC. 4. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within

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- the meaning of Section 6 of Article XIII B of the California Constitution.